

USA Accredited Seed Laboratory (ASL) Program

1 Purpose

The purpose of this document is to set forth the policies, procedures, and requirements of the USA Accredited Seed Laboratory (ASL) Program and for the independent process verification of participants in the ASL Program. The ASL Program is a voluntary, user-fee service available to seed testing laboratories. Seed testing laboratories, which meet all requirements of this program and successfully pass a USDA Process Verified Program Audit, will be able to represent themselves as a USA Accredited Seed Laboratory.

2 Scope

- 2.1 The ASL Program applies to seed laboratories seeking accreditation under this program. The USDA Agricultural Marketing Service (AMS) will conduct independent process verification audits of the seed laboratory's program documentation and procedures with regard to the ASL program.
- 2.2 Accreditation will be for germination and physical purity testing only and cover species contained within the Association of Official Seed Analysis (AOSA) Rules of Testing Seed and/or Federal Seed Act. A current listing of the varieties of seeds to be tested that are included in this program is posted on the ASL website at <http://www.ams.usda/lsg/arc/asl.com>.

3 Objective

The objective of the USA ASL program is to expand the choices for seed laboratories and provide an alternative program to current accreditations for U.S. Laboratories. The ASL program will increase the number of U.S. accredited seed laboratories, thereby enhancing seed movement both domestically and globally, through the verification process. Adherence to the program requirements and quality standards of the USDA Process Verified Program will further enhance the quality and consistency of seed testing in the U.S.

4 Reference Documents

- 4.1 ***ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures.***
- 4.2 ***ARC Procedure 1001 Process Verified Program***
- 4.3 ***Note: United States Seed Analyst Accreditation Standard, see link on <http://www.seedtechnology.net>***
- 4.4 ***International Organization for Standards (ISO) Guide 65, General requirements for bodies operating product certification systems.***
- 4.5 **Documents referenced above may be obtained from the USDA web site www.ams.usda.gov/lsg/arc/asl.htm**

5 Definitions

- 5.1 Accredited Seed Laboratory (ASL): Any seed-testing laboratory meeting all requirements of the ASL Program. USDA deems laboratories accredited upon implementation of a documented program that addresses the requirements of the ASL Program and upon successful completion of an audit by USDA, or by USDA, AMS Recognized Auditors.
- 5.2 Proficiency Testing: Accredited laboratories must satisfactorily participate annually in a recognized proficiency-testing program, within their chosen scope of crop accreditation. Recognized programs will include currently developed programs/or those to be developed and administered by *Association of Official Seed Analysis (AOSA)*, *Society of Commercial Seed Technologist (SCST)*, *Canadian Food Inspection Agency (CFIA)*, *International Seed Testing Association (ISTA)* or *United States Department of Agriculture (USDA)*. The laboratory may contract proficiency services if their chosen scope of crop accreditation is not offered in a recognized program or they may participate in a standard offered program that includes crop kinds beyond their chosen scope of accreditation.
- 5.3 Program Documentation: Documents and records prepared and maintained by ASL that describe and record the laboratory's procedures for ensuring samples received, tested, and identified conform to the ASL Program requirements. This documentation must be in the form of a well-defined quality manual, including controlled program documents and records that meet all ASL Program requirements.
- 5.4 Surveillance Audit: A review ASL's facilities, procedures, and records (1) to determine conformance with this Program, and (2) to verify the ASL's ability to meet all of the requirements of the USA ASL Program. These audits will be conducted by the USDA, AMS, Livestock and Seed Program, Audit, Review, and Compliance (ARC) Branch, or by USDA, AMS Recognized Auditors
- 5.5 Recognized Auditors: Audit, Review, and Compliance Branch Quality Systems Auditors, and audit programs that are approved by USDA AMS using International Organization for Standardization (ISO) Guide 65, General requirements for bodies operating product certification systems. Audit systems must include both a technical and systems auditing component, in accordance to ISO Guide 65 requirements.
- 5.6 Program Guidelines: The original program was developed and incorporated by a task force composed of affiliated seed associations and USDA representatives. A committee comprised of one member and one alternate appointed by the respective association from AOSA, SCST, Association of American Seed Control Officials (AASCO), Association of Official Seed Certification Agencies (AOSCA), American Seed Trade Association (ASTA) and USDA-AMS will make changes, as agreed upon, to the program once implemented.
- 5.6 Accreditation Auditor Authority: USDA-AMS will have the authority to approve, deny or suspend a laboratory's accreditation in accordance with the U.S.ASL Program guidelines.

- 5.7 **Product:** For the purpose of the ASL Program, the term “product” includes both samples and test reports.

6 Program Requirements

- 6.1 Eligible Seed Testing Laboratories must be:
- 6.1.1 An AOSA member in good standing, employing Certified Seed Analysts (CSA) with certification in purity and germination or a Registered Seed Technologist (RST) in good standing or;
 - 6.1.2 A SCST member in good standing employing a Registered Seed Technologist (RST).
- 6.2 Participation in this program is voluntary and not a requirement for AOSA or SCST membership.
- 6.3 Applications for accreditation will be reviewed by either the AOSA administrative office or the SCST Executive Director to verify individuals or laboratories are members in good standing.
- 6.4 ASLs must employ an accredited U.S. Seed Analyst (CSA or RST). In the event of personnel changes the laboratory must actively seek a replacement and obtain such within one (1) year to retain accreditation under this program. During this period, the ASL management must contact the USDA’s ARC Branch immediately for individual consideration to continue to operate under the ASL system. No ASL claims or certificates may be issued until this written approval is given.
- 6.5 ASLs must maintain an approved Quality Management System and Standard Operation Procedures that meet all the applicable elements as outlined in ***ARC Procedure 1001 Process Verified Program***. All program documentation must be available for review by the USDA Auditor, or its designee.
- 6.6 Prior to acceptance into the Program, ASLs must have satisfactorily participated in or completed an established proficiency program in regards to its chosen scope of accreditation. A maximum of three proficiency tests are required per year. Proficiency testing results must be submitted to the USDA-AMS on an annual basis.
- 6.7 Conformance with the ASL Program requirements will be determined through fee-for-service, process verified, surveillance audits conducted by USDA AMS, or its designee using the USA ASL Program, ***ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures*** and ***ARC Procedure 1001 Process Verified Program***
- 6.8 ASLs will be accountable to test seed in accordance with AOSA Rules for Testing Seeds or the Federal Seed Act.

7 Testing Laboratory Responsibilities

- 7.1 Request initial assessment by submitting the following to the USDA-AMS.
 - 7.1.1 A completed and signed *LS Form 313, Application for Service*.
 - 7.1.2 A cover letter requesting an ASL Program audit, to include chosen scope of accreditation.
 - 7.1.3 Program documentation used to ensure conformance to the applicable elements of ***ARC Procedure 1001, Process Verified Program*** and the ASL Program requirements.
- 7.2 Ensure that all persons with responsibilities for Program activities have been properly trained and have a complete understanding of all Program requirements relevant to their area of responsibility.
- 7.3 ASLs must conduct an internal audit annually and supply the results of internal audit to USDA AMS Washington, D.C. prior to its anniversary date listed on the USDA web site. Internal audits must review all activities within the scope of the accreditation and can be performed by the ASL or by an outside agency.
- 7.4 Address all non-conformances within the timeframe outlined in the audit report.
- 7.5 Comply with all provisions of this Program and applicable elements of ***ARC Procedures 1001, Process Verified Program***.
- 7.6 Maintain complete records demonstrating conformance with the ASL Program. Records shall be maintained for a minimum of three (3) years. Records can be disposed of at the beginning of the fourth year after the year in which they were created.
- 7.7 Provide any and all documents and records (written or electronic) necessary to verify conformance.
- 7.8 Provide USDA AMS auditor access to all areas of the facility that is requesting an accreditation status.
- 7.9 Immediately notify USDA AMS Washington, D.C., of any significant changes in the approved program documentation used to verify conformance to the ASL Program.
- 7.10 Notify USDA AMS Washington, D.C., to cancel service prior to the next surveillance audit when service is no longer desired.
- 7.11 Clearly identify the results of tests that fall within the accreditation guidelines in the seed lab report. The report must also identify as separate any tests that lie outside the scope of accreditation. (Suggested statement: “Physical purity, noxious weed and germination examinations were conducted in accordance with the AOSA Rules for Testing Seeds. All other tests or test deviations listed on this report are outside the scope of the US ASL Program”).

8 USDA AMS Responsibilities

- 8.1 Review submitted *LS Form 313, Application for Service* and program documentation.
- 8.2 Assign a qualified USDA ARC Branch auditor, or an approved Recognized Auditor chosen to perform an initial audit as soon as possible upon determining that the *LS Form 313 Application for Service* is complete and that the submitted program documentation meets the requirements of the ASL Program.
- 8.3 Conduct audits according to this Procedure, *ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures*, and *ARC Instructions 1001 Process Verified Program*.
- 8.4 Prepare a detailed report of the audit observations, findings, and a recommendation regarding the status of the ASL Program.
- 8.5 Forward the audit report and the final USDA-AMS decision to the ASL.
- 8.6 Ensure surveillance audits are performed as required by this Procedure and provide overall program review and approvals.
- 8.7 Maintain and publish the *Listing for the ASL Program* at www.ams.usda.gov/lsg/arc/asl.htm
- 8.8 Records should be maintained for three (3) calendar years after the year in which the external audit was conducted.

9 Surveillance Audits

- 9.1 *ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures* and the requirements outlined in this Program will be used to assess seed laboratories.
- 9.2 All ASLs will be audited at least every three (3) years. More frequent audits may be conducted if either numerous minor nonconformances or a major nonconformance are identified during an audit.
- 9.3 USDA AMS reserves the right to conduct a case specific surveillance audit at any time at the cost of the participant. A surveillance audit could be triggered by a written complaint, which has been investigated and deemed valid by USDA, or a non-conformance issue relating to the audit process.
- 9.4 Program audits will be conducted by USDA AMS or its designee and will including both a technical and system audit component,

10 Approval Procedures

ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures, ARC Procedure 1001 Process Verified Program, and the requirements outlined in this Procedure will be used to approve or deny seed laboratories.

- 10.1 Approval. A seed laboratory that has been found to conform to this Program and the approved program documentation will be considered accredited. Once accredited, USDA AMS will post the seed laboratory's information on the *Listing of ASL Programs*. The Accredited Seed Laboratory is authorized to use the following statement on laboratory documentation and point of sale information, "USA Accredited Seed Laboratory as defined at <http://www.ams.usda.gov/lsg/arc/asl.htm> ."
- 10.2 Denied Approval. USDA AMS may deny eligibility for any of the following reasons:
 - 10.2.1 Failure to adequately address any requirements.
 - 10.2.2 Failure to demonstrate capability to meet any requirement.
 - 10.2.3 Finding of a hold point to stated procedures.
 - 10.2.4 Denying access to a seed laboratory's facilities, documentation, or records within the scope of the requested audit.
 - 10.2.5 Presenting false or misleading information to USDA personnel or agent of the USDA.
- 10.3 Suspending Approval. USDA AMS may suspend eligibility and remove an ASL from the program for any of the following reasons:
 - 10.3.1 Failure to follow requirements set forth in this Procedure or the approved program documentation.
 - 10.3.2 Implementing significant changes to approved program documentation without prior written notification to USDA AMS.
 - 10.3.3 Misrepresentation of accreditation status or test results.
 - 10.3.4 Presenting false or misleading information to USDA or its designee.
 - 10.3.5 Confirmed finding of non-conforming activities in respect to the ASL Program. Upon confirming the violation, USDA AMS will suspend the ASL pending a complete investigation.
 - 10.3.6 Denying access to laboratory facilities, documents, or records within the scope of the requested audit.
 - 10.3.7 Failure to respond to non-conformances in the timeframe provided.
 - 10.3.8 Failure to pay USDA AMS audit fees.
 - 10.3.9 Failure to remain a member in good standing in AOSA or SCST, employing CSA's with certification in purity, germination and noxious weed testing; or a member in good standing in SCST, employing an RST.
 - 10.3.10 USDA AMS will notify the ASL in writing of the suspension and the details on actions required to regain eligibility status.

10.4 Cancellation. Accredited seed laboratories may cancel service at any time by notifying USDA AMS in writing. ASL that cancels service will be removed from the *List of Accredited Seed Laboratory (ASL) Program*. ASLs that cancel service must reapply and be reassessed through an audit before they will be returned to the appropriate Official Listing.

10.5 Appeals, Complaints, and Disputes. Applicants have the right to question or appeal any adverse audit finding or decisions issued by the Quality System Verification Program manager. Appeals, complaints, and disputes must be submitted in writing to the ARC Branch Chief, Washington, DC, within 30 days of the date of the official report or the letter rendering the findings or decisions of the audit or complaint. Request for appeals must include: 1) The basis for the appeal, complaint or dispute; 2) The requested alternative decision or actions. Upon receipt of item 1 or 2 The ARC Branch Chief will review any request for action and notify the applicant of the final decision within 30 working days of the receipt of the request. Any suspensions or denied approvals will remain in effect pending the outcome of the appeal.

11 ARC Branch Contact Information

All program documentation, updates, internal reviews and proficiency testing results should be submitted to the following address:

USDA, AMS, LS, ARC Branch
Stop 0294, Room 2627-S
1400 Independence Avenue, SW
Washington, DC 20250
Phone: (202) 720-1124
Fax: (202) 690-3428 or (202) 690-1038

12 Publication of Approved Status

Information about each accredited seed laboratory will be posted on the USDA, AMS, Internet website at <http://www.ams.usda/lsg/arc/asl.com>. Information posted will include the name, address and scope of testing.

13 Confidentiality

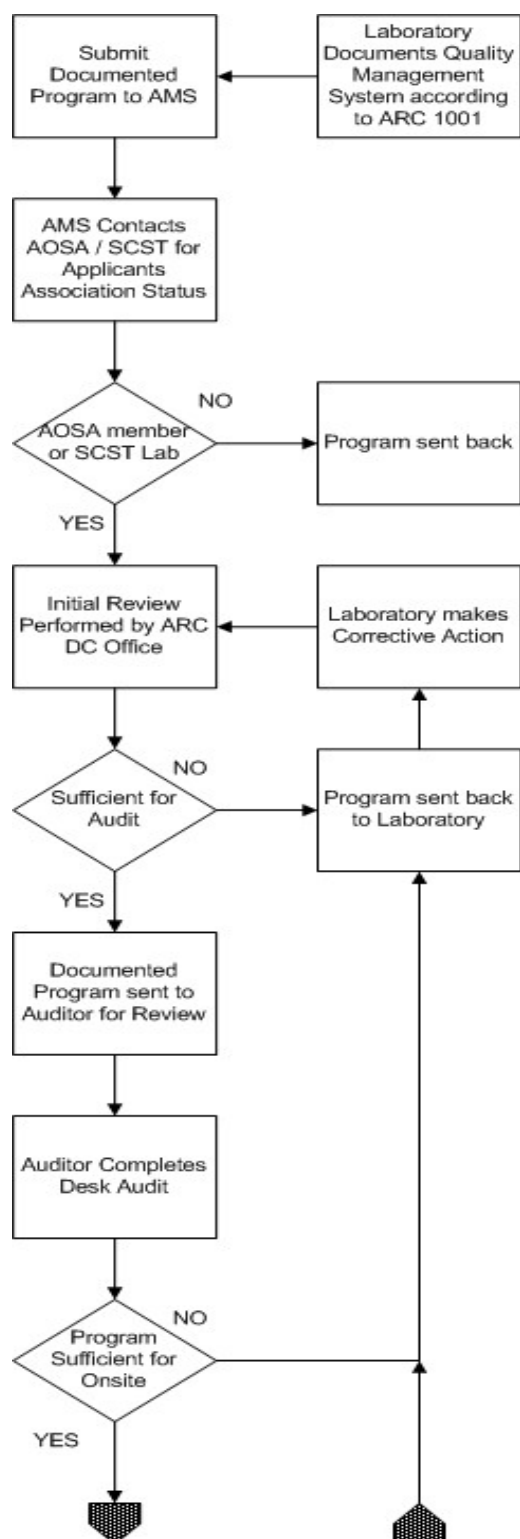
All materials submitted by applicants and maintained by USDA AMS are subject to disclosure under the Freedom of Information Act. The Freedom of Information Act applies to documents that are in the control of or maintained by a government agency. USDA AMS does not maintain program manuals submitted by applicants. These manuals are reviewed by a branch auditor and returned to the applicant upon completion of the audit process. The ARC Program Manager will make appropriate provisions to protect proprietary information from disclosure to the extent possible under existing Federal laws. Any portion of the program documentation that the applicant considers proprietary must be identified at the time the information is submitted along with written justification why said documents should not be release to or reviewed by the public. Any information deemed a trade secret or confidential business information can not be released to the public.

14 Proficiency Testing Groups**Crop Groupings of Proficiency Testing – USA ASL Program**

Kind	Species
Grasses	Agropyron, Agrostis, Alopecurus, Andropogon, Anthoxanthum, Arrhenatherum, Axonopus, Bothriochloa, Bouteloua, Bromus, Cenchrus, Chloris, Cynodon, Cynosurus, Dactylis, Echinochloa, Eragrostis, Ehrharta, Elymus, Elytrigia, Festuca, Holcus, Lolium, Melinis, Paspopyrum, Paspalum, Phalaris, Phleum, Pennisetum, Piptatherum, Poa, Pseudoroegneria, Setaria, Sorghastrum, Urochloa, Zoysia
Cereals & Other Crops	Avena, Carthamus, Fagopyrum, Gossypium, Helianthus, Hordeum, Linum, Oryza, Secale, Sorghum, Triticosecale, Triticum, Zea
Legumes	Alysicarpus, Arachis, Astragalus, Cicer, Crotalaria, Cyamopsis, Desmodium, Glycine, Hedysarum, Indigofera, Lablab, Lathyrus, Lens, Lotus, Lespedeza, Lupinus, Medicago, Melilotus, Mucuna, Onobrychis, Phacelia, Phaseolus, Pisum, Pueraria, Securigera, Trifolium, Vicia, Vigna
Vegetables, Flowers & Herbs	Abelmoschus, Allium, Anethum, Anthriscus, Apium, Arctium, Asparagus, Atriplex, Atropa, Bassia, Beta, Borago, Brassica, Camelina, Campanula, Capsicum, Carum, Chrysanthemum, Cichorium, Citrullus, Claytonia, Corchorus, Coriandrum, Cucurbita, Cucumis, Cuminum, Cynara, Daucus, Eruca, Foeniculum, Fragaria, Hyssopus, Ipomoea, Kochia, Lactuca, Lavandula, Lepidium, Levisticum, Lycopersicum, Marrubium, Matricaria, Melissa, Mentha, Nasturtium, Nicotiana, Nigella, Ocimum, Oenothera, Origanum, Papaver, Pastinaca, Petroselinum, Phacelia, Physalis, Pimpinella, Portulaca, Rheum, Raphanus, Ricinus, Rosmarinus, Rumex, Ruta, Salvia, Sanguisorba, Satureja, Scorzonera, Sesamum, Sinapis, Solanum, Spinacia, Stylosanthes, Taraxacum, Tetragonia, Thymus, Tragopogon, Tropaeolum, Valerianella
Trees & Shrubs	Abies, Acer, Betula, Calocedrus, Cedrus, Chamaecyparis, Cornus, Cupressus, Fraxinus, Larix, Liquidambar, Liriodendron, Malus, Nyssa, Picea, Pinus, Platanus, Populus, Prunus, Pseudotsuga, Pyrus, Quercus, Robinia, Sequoia, Sequoiadendron, Thuja, Tsuga, Ulmus

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Approved 04 01 2005 JLR

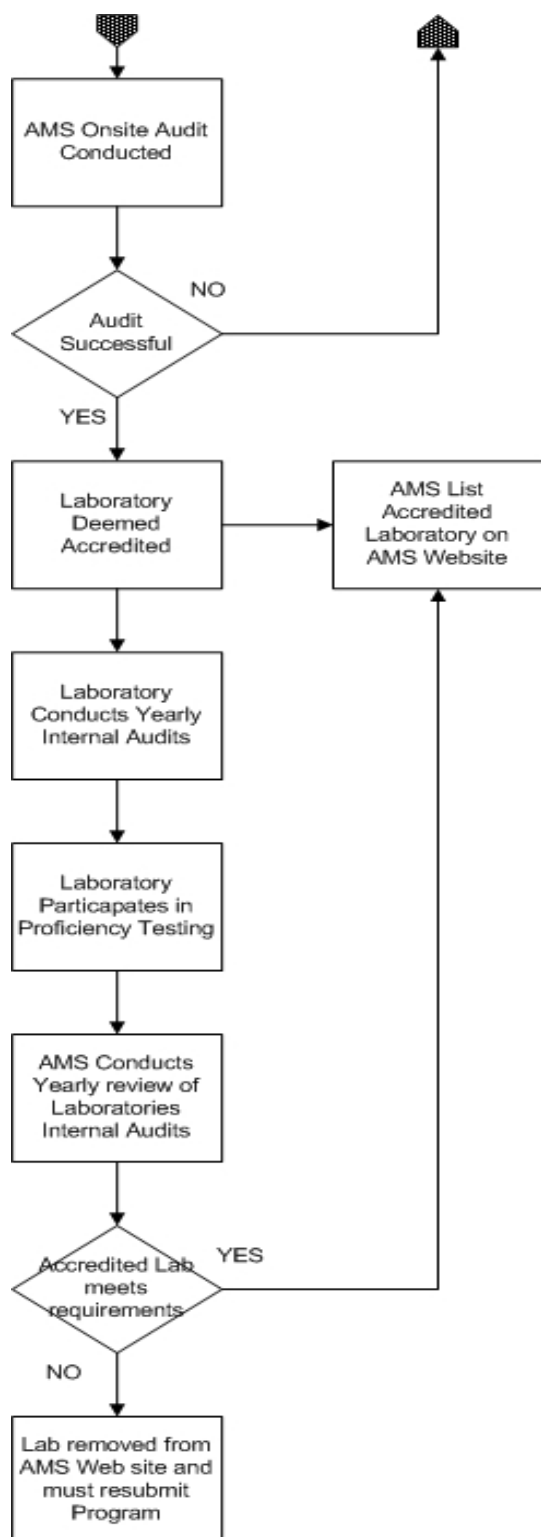


USA Accredited Seed Laboratory (ASL) Program

1. The applicant lab documents its Quality Management (QM) system according to *ARC 1001, Process Verified Program* and current *USA ASL Procedure*.
2. The lab requests an initial assessment by submitting the following to the ARC Branch Washington, D.C., office.
 - A completed and signed *Application for Service, LS Form 313*,
 - A cover letter requesting an ASL Program audit and defining the scope of accreditation.
 - The Quality Management program documentation used to ensure conformance to the applicable elements of *ARC Instruction 1001, Process Verified Program* and the ASL Program requirements.
3. AMS contacts AOSA or SCST to verify that the applicant meets the “member in good standing” requirement.
4. The ARC Washington, DC office performs the initial review. If the submitted program is sufficient, it is then sent to an auditor.
5. AMS will assign a qualified USDA ARC Branch auditor, or approved recognized audit program chosen to perform an audit as soon as possible upon determining that the *Application - LS Form 313* and QM program documentation is sufficient.
6. An auditor will complete a desk audit of the program, interacting with the laboratory as necessary.
7. The auditor will schedule the onsite visit once the program is determined to be sufficient.
8. All audits will be conducted according to *ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures*, and *ARC Instructions 1001 Process Verified Program*.

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Issue Date : April 01, 2005



9. AMS will prepare a detailed report of the audit observations, findings, and a recommendation. AMS will then forward the audit report and the final decision to the accredited laboratory. AMS will ensure surveillance audits are performed as required by this procedure and provide overall program review and approvals.

10. The lab must address any nonconformances found during the audit within a reasonable time frame.

11. Approval. A seed laboratory that conforms to the ASL procedure and their approved Quality Management program documentation will be considered accredited. Once accredited, the ARC Branch will post the seed laboratory's information on the *Official Listing of Accredited Seed Laboratory (ASL) Program*.

12. Accredited seed laboratories must conduct an internal audit yearly and supply a copy of the results to USDA AMS Washington, D.C. prior to their anniversary date on the USDA official web listing. Internal audits must review all activities within the scope of the accreditation and can be self-performed or contracted with an outside agency.

13. Accredited seed laboratories must participate in recognized proficiency testing within their chosen scope of accreditation.

14. Accredited seed laboratories will be audited every three (3) years. However, more frequent audits may be conducted if either numerous continuous improvement points or a hold point are identified during any audit.

15. USDA/AMS reserves the right to conduct a case specific surveillance audit during the three (3) year period, at the cost of the participant. A surveillance audit could be triggered by a written complaint, which has been investigated and deemed valid by USDA, or a nonconformance issue relating to the approval process.

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